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K100606

510(k) SUMMARY
REDENT NOVA's VATEA Endodontic Irrigation System

Submitter's Name, Address, Telephone Number, Contact Person: and Date Prepared

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MAY 2 8 2010

Date Prepared: May 25, 2010

Name of Device and Name/Address of Sponsor:

VATEA Endodontic Irrigation System

ReDent Nova Ltd.
15 Hataasia street
P.O.B 4159
Raanana
43000, Israel

Common or Usual Name

VATEA Endodontic Irrigation System

Classification Name

Name:	Dental Handpiece & Accessories
Product code:	NYL
Classification panel:	872.4200
Class:	I
Panel:	Dental

Predicate Devices

Quantec-E Irrigation System (K991035), Sybron Dental Specialties Inc., CA, US.

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Intended Use / Indications for Use

The VATEA system is intended to be attached to dental handpieces to deliver irrigation during endodontic procedures.

Technological Characteristics

The VATEA device is a self contained, digitally-controlled fluid delivery unit consisting of a pump unit console, irrigation reservoir and tubing intended to be connected to an endodontic file. The device consists of a positive pressure peristaltic pump console with control panel, LCD display, irrigation reservoir, disposable silicone tubing, and a footswitch control to provide irrigation during endodontic procedures. One end of the silicone tubing connects to the VATEA and the other end connects to the dental handpiece using a silicone ring. The silicone ring is elastic, and may be stretched to accommodate a full range of dental handpieces used in endodontic procedures. The irrigation reservoir is filled as needed with sodium hypochlorite solution for irrigation during endodontic procedures. The irrigation fluid is pumped from the reservoir and then out of the silicone tubing, along the dental file into the pulp chamber of the tooth. The silicone tubing for the delivery of the irrigation fluid and the silicone ring connecting the pump to the dental handpiece are disposable and replaced after each treatment.

The irrigation fluid flow may be switched on and off with a footswitch that is connected to the VATEA. The flow rate and operation status of the device are displayed on the LCD screen on the control panel. The default flow rate is 0, and the user must increase the flow rate using the - / + buttons on the control panel to initiate flow of the irrigation fluid. The irrigation fluid flow rate may be adjusted between 1 and 10 ml/min in increments of 1 ml/min using the - /+ push-button control on the control panel.

The VATEA is an electronically operated device, powered by a rechargeable battery.

Performance Characteristics

The company performed the following testing to evaluate the safety and performance of the device:

- IEC 60601-1 Medical Electrical Equipment Part 1, General Requirements for Safety.
- IEC 60601-1-2 Medical Electrical Equipment, General Requirements for Safety. Collateral Standard: Electromagnetic Compatibility- requirements and tests.
- Performance validation:
    - Verification of flow rate – Actual irrigant flow rate matched the displayed flow rate
    - Battery indication and life time - With batteries fully charged, the system can operate without the charger for 4 continuous hours at maximum output.

Performance data establishes that the VATEA has comparable performance and safety as compared to its claimed predicate device.

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Substantial Equivalence

The VATEA has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the VATEA and its predicate device raise no new issues of safety or effectiveness. Preclinical performance data demonstrates that the VATEA is as safe and effective as the Quantec-E. Thus, it can be concluded that the VATEA is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ReDent Nova Limited
C/O Jonathan S. Kahan
Hogan & Hartson LLP
Columbia Square, 555 13th Street, NW
Washington, District of Columbia 20004

MAY 2 8 2010

Re: K100606
Trade/Device Name: VATEA Endontic Irrigation System
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: NYL
Dated: May 25, 2010
Received: May 25, 2010

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Indications for Use Statement

510(k) Number (if known):_____

Device Name:

VATEA Endodontic Irrigation System

Indications for Use:

The VATEA system is intended to be attached to dental handpieces to deliver irrigation during endodontic procedures.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ron Mehey for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100606

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